PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P5841WO0	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 02/31816	International filing date *(day/month/year)* 04.10.2002	Priority date *(day/month/year)* 04.10.2002
International Patent Classification (IPC) or both national classification and IPC A61B19/00		
Applicant MED-TEC IOWA, INC. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.03.2004	17.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kurze, V Telephone No. +49 89 2399-7380

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 02/31816

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-4 as originally filed

Claims, Numbers

1-9 filed with telefax on 07.09.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☒ the claims, Nos.: 10-17
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

   see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I

Basis of the report

The amendments of claim 1 are based on original claim 1 and on the description, p.1, l.15-16. Claims 2-9 correspond to the originally filed claims 2-9.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Subject-matter
   The invention concerns a patient restraint member made of thermoplastic material to be formed over a part of a patient's body.

2. Novelty (Article 33(2) PCT)
   Document D1 is considered the closest prior art. It does not show "spaced apart groups of perforations punched or moulded in the sheets to reduce the force necessary to form, minimized the heat transferred to the patient, and to minimize the shrinkage of the thermoplastic material".

   D2 shows holes which are not punched or moulded in a sheet. Its teaching is further away from the current invention.

3. Inventive step (Article 33(3) PCT)
   The holes shown in D1 serve a completely different purpose, namely for attaching the sheet to a table or holder. It does not address the problem of reducing the force necessary to form, neither does it address the problem of minimizing heat transfer to the patient or to minimize the shrinkage of the material.

   The restraint member of Document D2 is made of several different materials and therefore applies a very different technique. It does not suggest using punched or moulded holes in a single sheet. Therefore, a person skilled in the art, when starting with the device of D1, would not consult the teachings of D2 in order to solve the problems mentioned above.

   Therefore, claim 1 and by virtue of their dependence, claims 2-9 involve an

inventive step.

4. Clarity (Article 6 PCT)
The differentiating features are functional features concerning the place, size, and number of the "spaced apart groups of perforations". A skilled person would readily know how to achieve the desired effect by choosing the appropriate parameters. Therefore, these features are clear and thus the claims are clear.

Agent's Ref. No. P5841WO0

What is claimed is:

1. A patient restraint member for use in medical procedures, comprising: a sheet of thermoplastic material that can be softened upon heating so as to be formable into a shape corresponding to a patient's body part to be restrained and setting upon cooling to retain the shape; spaced apart groups of perforations punched or molded in the sheets to reduce the force necessary to form, to minimize the heat transferred to the patient, and to minimize the shrinkage of the thermoplastic material; and solid bands extending between the groups of perforations.

2. The patient restraint member of claim 1 wherein the sheet has a perimeter edge and the bands extend inwardly from the edge.

3. The patient restraint member of claim 2 wherein the bands intersect at a location spaced inwardly from the edge.

4. The patient restraint member of claim 2 wherein the bands extend perpendicular to the edge.

5. The patient restraint member of claim 2 wherein the bands extend in a non-perpendicular angle from the edge.

6. The patient restraint member of claim 2 wherein the bands extend completely across the sheet.

7. The patient restraint member of claim 1 wherein the sheet has a perimeter edge without perforations.

8. The patient restraint member of claim 1 wherein the solid bands extend across the sheet.

9. The patient restraint member of claim 1 wherein the spaces between the groups of perforations define the solid bands.